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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,760	09/29/2006	Motoyoshi Inooka	8156/88314	4637

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,760	INOOKA ET AL.	
	Examiner	Art Unit	
	Gregg Polansky	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/06 and 4/04/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Claims

1. Applicants' Information Disclosure Statements, filed 9/29/2006 and 4/04/2007, are acknowledged and have been reviewed.

2. Claims 1-13 are pending.

3. Claims 1-13 are under consideration.

Claim Rejections - 35 USC § 112 and 35 USC § 101

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 5 recites the broad recitation of a packaging container, which has an average light transmittance of 20% or lower in the wavelength range from **350 nm to 450 nm**, and the claim also recites a packaging container, which has an average light transmittance of 20% or lower in the wavelength range from **365 nm to 430 nm**, and an average light transmittance of 20% or lower in the wavelength range from **350 nm to 430 nm**, which are the narrower statements of the range/limitation.

8. Claim 12 provides for the "[u]se of the packaging container through which the contents are visible and which blocks light in the wavelength range from 365 nm to 430 nm for inhibiting the degradation of at least one member selected from the group consisting of tranilast and a salt thereof when exposed to light", and Claim 13 provides for the "[u]se of the packaging container through which the contents are visible and which blocks light in a wavelength range from 365 nm to 430 nm for preventing the degradation of a pharmaceutical preparation comprising at least one member selected from the group consisting of tranilast and a salt thereof when exposed to light", but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12 and 13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claim recites "[a] pharmaceutical product according to Claim 1, wherein the pharmaceutical preparation further comprises at least one member selected from the group consisting of berberine, B2 vitamins, hesperidin, oxyquinoline, B12 vitamins, **derivatives thereof**, and salts thereof". There is insufficient written basis for derivatives of berberine, B2 vitamins, hesperidin, oxyquinoline, and B12 vitamins in the specification.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Elli Liily*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Elli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any structural characteristics, chemical formula, names or physical properties of derivatives of berberine, B2 vitamins, hesperidin, oxyquinoline, and B12 vitamins, aside from a broad recitation that such are contemplated for use in the invention. As such, it is not apparent that Applicant was

actually in possession of, and intended to use within the context of the present invention, any specific derivatives of berberine, B2 vitamins, hesperidin, oxyquinoline, and B12 vitamins at the time the present invention was made.

11. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **inhibiting** the photodegradation of tranilast, does not reasonably provide enablement for **preventing** the photodegradation of tranilast. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to "a packaging container through which the contents are visible and which blocks light in a wavelength range from 365 nm to 430 nm for preventing the degradation of a pharmaceutical preparation comprising at least one

member selected from the group consisting of tranilast and a salt thereof when exposed to light".

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Hori et al. (Chem. Pharm. Bull. 47(12), 1999) teach photodegradation of tranilast and UV-absorbing agents used to inhibit it (*see* Abstract). They also teach the use of light-resistant packaging consisting of aluminum foil, colored glass and UV-absorbing agent impregnated films to inhibit photodegradation (*see* page 1713, 2nd paragraph).

(5) The relative skill of those in the art:

The level of ordinary skill in the art is that of a Ph.D. medicinal chemist or pharmacist.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The Specification has provided guidance for **inhibiting** the photodegradation of tranilast caused by light in the 350 nm to 450 nm wavelength range.

However, the Specification does not provide guidance for **preventing** the photodegradation of tranilast.

Table 2 of the Specification provides degradation data for tranilast, contained in containers with various light transmission properties, exposed to high intensity light. The data demonstrate the effectiveness of containers characterized by reduced transmission of light in the 350 nm to 450 nm range, at reducing degradation of tranilast; up to 96.2% of the pre-irradiation tranilast remained after the light irradiation. However, based on this data, some degradation did occur.

The Merriam-Webster Online Dictionary (http://m-w.com/dictionary/prevent) defines prevent as "to keep from happening or existing" or "to deprive of power or hope of acting or succeeding". Based on this definition and the data recited in the instant Specification, the Applicants have not demonstrated a **prevention** of the photodegradation of tranilast.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, and the generally accepted definition of the word "prevent", and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al. (JP 2002-234837 Abstract and Machine Translation) in view of Hori et al. (Chem. Pharm. Bull. 47(12), 1999) and Healy et al. (U.S. Patent Number 6,066,374).

Koichi et al. teach externally applied, aqueous preparations of tranilast with a concentration of 0.05% to 30% (*see* page 9, claims 1 and 5). Koichi et al. also teach that tranilast is used as an anti-allergic drug for the treatment of allergic diseases, and keloid and hypertrophic scars (*see* page 1, paragraph 4). These teaching satisfy the limitations recited by instant Claims 8-10.

Koichi et al. does not teach the photodegradation of tranilast or a light-resistant packaging container.

Hori et al. teach the photodecomposition of tranilast aqueous solution and oily gel (*see* page 1714, "Photostability of TL", and figure 2A). Hori et al. teach light-resistant packaging consisting of aluminum foil, colored glass, and UV-absorbing agent impregnated films to inhibit photodegradation of drugs (*see* page 1713, 2nd paragraph).

The reference also teaches the use of UV-absorbing agents added to tranilast oily gels to inhibit the photodegradation of the tranilast (*see* Abstract).

Hori et al. does not teach a packaging container with the light transmission properties recited in the instant claims.

Healy et al. teach "a transparent, light resistant container for the storage of medicinal agents" that permits transmission of no more than 10% of light having a wavelength of between 290 nm and 450 nm (which totally encompasses the instant invention light transmission ranges), while still permitting transmission of adequate visible light to allow external visual inspection of printed characters on the medicinal agents stored in the container (*see* Abstract and column 7, Example 3). Instant Claim 6 requires an average light transmittance of 30% or higher in the wavelength range of 455 nm to 780 nm. This is the wavelength range that allows the contents of the container to be visually inspected (*see* Instant Specification, page 12, last paragraph). This property of the container recited in the instant disclosure, is taught by Healy et al., as demonstrated by the ability to read printed characters on medicinal agents stored in the Healy et al. recited container (*supra*) and by the graph showing a plot of the percentage of transmission of light as a function of wavelength through the wall of the preferred container taught by Healy et al. (*see* the Healy et al., Figure). Healy et al. also teach that the United States Pharmacopeia (USP) regulations require that "medicinal agents which are intended for oral or topical administration must be stored in a container which permits transmission into the container of no more than 10% of ultraviolet and visible light having a wavelength of between 290 nm to 450 nm" (*see* column 1, 2nd paragraph).

It would have been obvious to one of average skill in the art (such as a Ph.D. medicinal chemist or pharmacist) to combine the above teachings, being so motivated by a need to dispense tranilast in a container that protects it from photodegradation and yet still allowing visible inspection of the contents. Further motivation would come from the USP storage container light transmission regulations taught by Healy et al.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al. (JP2002-234837) in view of Hori et al. (Chem. Pharm. Bull. 47(12), 1999) and Healy et al. (U.S. Patent Number 6,066,374) as applied to Claims 1-6 and 8-13 above, and further in view of Michitoku et al. (JP 04295428 Abstract).

Instant Claim 7 is drawn to a pharmaceutical product according to Claim 1, wherein the pharmaceutical preparation further comprises (in addition to the tranilast

recited in Claim 1) at least one member selected from the group consisting of berberine, B2 vitamins, hesperidin, oxyquinoline, and BI2 vitamins.

The teachings of Koichi et al., Hori et al., and Healy et al. have been presented above.

Michitoku et al. teach hesperidin as a useful anti-allergic and anti-inflammatory agent (*see* Abstract).

Since inflammation is a common characteristic of an allergic reaction (e.g., bug bite), it would have been obvious to one of ordinary skill in the art to combine tranilast (anti-allergen) with hesperidin (anti-allergen and anti-inflammatory) to try to improve upon the therapeutic benefits of tranilast administered by itself.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

17. Claims 1-13 are rejected.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GP

Phyllis Spivack
9/9/07

PHYLLIS SPIVACK
PRIMARY EXAMINER